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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,523	10/24/2003	Nicholas G. Bacopoulos	24852-501 CIP4	9840

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Ivor R. Elrifi
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY AND POPEO P.C
666 Third Avenue, 24th Floor
New York, NY 10017

EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,523	BACOPOULOS ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-28,30-36,38-43,45-50,52-57,59-63,95-142 and 157-178* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-28,30-36,38-43,45-50,52-57,59-63,95-142 and 157-178* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 10/6/2006, have been fully considered and they are persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. Upon further consideration the following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Continued Examination Under 37 CFR § 1.114

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submissions filed on 9/19/2006 and 10/10/2006 have been entered.

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is James D. Anderson, Ph.D. Contact information is provided at the end of this Office Action.

Status of the Claims

Claims 1-10, 12-28, 30-36, 38-43, 45-50, 52-57, 59-63, 95-142 and 157-178 are currently pending and are the subject of this Office Action. This is the first Office Action following submission of a request for continued examination under 37 CFR § 1.114.

Information Disclosure Statement

Examiner has considered the references disclosed in the information disclosure statements (IDS) submitted on 7/25/2006 to the extent that each reference cited therein is a proper citation. Please see attached PTO Form 1449.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim contains parenthetical information. It is not clear if this information (*i.e.* Burkitt's type leukemia) is intended to be a claim limitation. If it is a claim limitation, it is not clear if it only applies to sub-type L3 and not to sub-types L1 and L2 ALL.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-10, 12-28, 30-36, 38-43, 45-50, 52-57, 59-63, 95-96, 98, 100, 102-104, 106, 108, 110-112, 114, 116, 118-120, 122, 124, 126-128, 130, 132, 134-136, 138, 140, 142, 157, 160, 163, 166, 169, 172, 175 and 178 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DiMartino *et al.* (U.S. Patent No. 6,905,669) (previously cited) in view of Richon *et al.* (US 2003/0235588 A1; Published Dec. 25, 2003).[1]

DiMartino *et al.* disclose methods of treating cancer by administering to a patient in need thereof an effective amount of a pharmaceutical composition containing a DNA methylation inhibitor and a histone deacetylase inhibitor (HDAC). Specific examples of HDAC inhibitors that may be used in the cancer treatment methods include the instantly claimed SAHA (col. 5, lines 43-45). Examples of cancers include hairy cell tumors, acute and chronic lymphocytic

[1] Richon *et al.* qualifies as prior art under 35 U.S.C. § 102(e) as it claims priority to U.S. Provisional Application No. 60/357,383, filed Feb. 15, 2002.

tumors, acute myeloid leukemia, chronic myelogenous leukemia, acute promyelocytic leukemia and acute lymphoblastic leukemia (col. 17, lines 35-67; col. 18, lines 1-26). The HDAC inhibitors may be administered orally, parenterally or may be administered in slow release formulations (col. 20, lines 56-59; col. 21, lines 7-8). DiMartino *et al.* do not explicitly disclose that the HDAC inhibitors, alone, *i.e.* when not combined with the DNA methylation inhibitor, may be administered to treat leukemia. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat cancer such as leukemia with SAHA, because DiMartino *et al.* suggest that, individually, the HDAC inhibitors demonstrate anticancer activity, and one of ordinary skill in the art would reasonably expect HDAC inhibitors to be therapeutically effective against leukemia. Also, please note that applicant's claims recite "comprising" language. According to MPEP § 2111.03, "[t]he transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, *e.g.*, *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ 2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495,501, 42 USPQ 2d 1608, 1613 (Fed. Cir. 1997) ("'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795,803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Thus, since the pending claims

are open-ended due to the use of "comprising" language, they do not exclude the additional DNA methylation inhibitors taught by DiMartino *et al.*

DiMartino *et al.* do not specifically disclose applicant's oral doses of SAHA or claimed timing of administration. However, since therapeutic efficacy is related to the amount (dosage) of active agent administered as well as timing of administration, it would have been obvious to one of ordinary skill in the art to further modify the methods of DiMartino *et al.* such that the HDAC inhibitors are administered in an amount and for a period of time effective to optimize treatment of the various forms of leukemia. Such optimization of administration schedules is routine in the art of chemotherapy. Applicants have argued that DiMartino *et al.* do not disclose the oral doses of SAHA instantly claimed. As such, applicants argue that DiMartino *et al.* do not teach or suggest all of the claim limitations. Applicant's arguments are persuasive with respect to the DiMartino reference, however, when taken together with Richon *et al.*, evidence is provided that the instantly claimed oral doses of HDAC inhibitors, including SAHA were known in the art.

Richon *et al.* disclose methods of treating thioredoxin (TRX)-mediated diseases by administering to a subject in need of such treatment a therapeutically effective amount of a HDAC inhibitor or a pharmaceutically acceptable salt or hydrate thereof (Abstract). Elevated levels of TRX have been found in cancer. As such, TRX can "stimulate proliferation of a wide variety of cancer cell lines and inhibit apoptosis in cells over expressing the protein" (page 1, ¶ [0007]). The invention discloses the use of HDAC inhibitors that can alter the expression of a TRX-binding protein (*e.g.* TRX-binding protein-2 or TBP-2), which in turn can lead to altered TRX/TBP-2 cellular binding interaction, resulting in an increase or decrease in the level or

activity of cellular TRX (pages 1-2, ¶ [0011]). Thus, the invention relates to the use of HDAC inhibitors in a wide variety of TRX-mediated diseases and conditions, including diseases characterized by cellular hyperproliferation (*id.*). The inventors discovered that HDAC inhibitors induce expression of a TRX-binding protein, which is associated with a decrease in the level or activity of TRX resulting from interaction of TRX with the TRX-binding protein (page 2, ¶ [0012]). HDAC inhibitors, therefore, can be used to treat diseases characterized by "an increased level or activity of TRX" (page 2, ¶ [0013]). HDAC inhibitors effective at treating TRX-mediated diseases include hydroxamic acid derivatives (page 2, ¶ [0021]), including the instantly claimed SAHA (*id.* at ¶ [0023] and page 3, ¶ [0030]). Pharmaceutically acceptable salts of HDAC inhibitors are recited at page 17, ¶ [0156]. Hydrates of HDAC inhibitors are recited at page 17, ¶ [0157]. HDAC inhibitors of the invention can be administered in oral forms including tablets, capsules, pills, powders, granules, elixers, tinctures, suspensions, syrups, and emulsions (page 18, ¶ [0176]). Oral dosages of the HDAC inhibitors can range between about 2 mg to about 2000 mg per day and specific oral dosages of 2, 20, 200, 400, 800, 1200, 1600, and 2000 mg per day are disclosed (page 19, ¶ [0181]). The reference thus discloses the oral dosages of HDAC inhibitors, including the instantly claimed SAHA. The total daily amount of HDAC inhibitor can be administered in multiple doses, such as twice, three, or four times per day (*id.*). The oral formulations can be in the form of tablets or capsules and combined with pharmaceutically acceptable inert carriers, including microcrystalline cellulose (page 20, ¶ [0191]). In addition, suitable binders, lubricants and disintegrating agents can be included in the formulation (*id.*). Suitable disintegrating agents include the instantly claimed sodium croscarmellose (*id.*). Suitable lubricants include the instantly claimed magnesium stearate (*id.*).

Thus, Richon *et al.* disclose methods of administering the instantly claimed HDAC inhibitor in the doses and formulations instantly claimed.

It would have been *prima facie* obvious to use the oral doses of SAHA disclosed in Richon *et al.* in the methods of treating leukemia disclosed in DiMartino *et al.* The skilled artisan would have been motivated to determine suitable oral doses of SAHA given the disclosure of DiMartino *et al.*, *i.e.* through no more than routine experimentation, one skilled in the art looking for a treatment of leukemias and wanting to orally administer SAHA, would be motivated to find prior art that disclosed oral doses of SAHA suitable for treating patients. The skilled artisan would have been imbued with at least a reasonable expectation of therapeutic efficacy in treating leukemia with the oral doses of SAHA disclosed in Richon *et al.* Further, as discussed *supra*, since therapeutic efficacy is primarily related to the amount (dosage) of active agent administered, as well as timing of administration, it would have been obvious to one of ordinary skill in the art to further modify the methods of DiMartino *et al.* and Richon *et al.* such that the HDAC inhibitors are administered in an amount and for a period of time effective to optimize treatment of the various forms of leukemia.

Claims 97, 99, 101, 105, 107, 109, 113, 115, 117, 121, 123, 125, 129, 131, 133, 137, 139, 141, 158-159, 161-162, 164-165, 167-168, 170-171, 173-174 and 176-177 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiMartino *et al.* and Richon *et al.* as applied to claims 1-10, 12-28, 30-36, 38-43, 45-50, 52-57, 59-63, 95-96, 98, 100, 102-104, 106, 108, 110-112, 114, 116, 118-120, 122, 124, 126-128, 130, 132, 134-136, 138, 140, 142, 157, 160, 163, 166,

169, 172, 175 and 178 above, and further in view of Kelly *et al.* (Proc. American Society of Clinical Oncology, 2001, 20:87a, Abstract No. 344) (cited by applicants in IDS filed 4/6/2004).

The instant claims recite specific administration schedules of oral SAHA.

DiMartino *et al.* and Richon *et al.* disclose as discussed *supra*. The combined references do not disclose the specific administration schedules instantly claimed.

However, Kelly *et al.* is provided as evidence that optimizing administration schedules of SAHA is well within the level of ordinary skill in the art and is therefore routine optimization. The reference discloses the optimization of dosing regimes for intravenous SAHA. SAHA was administered to patients at varying doses as a 2-hr. IV infusion for three consecutive days every 21 days and for five consecutive days for 1-3 weeks.

The skilled artisan would have been highly motivated to determine the optimal dose and schedule of administration of SAHA for the treatment of leukemia. It is noted that optimization of drug dosing and scheduling is routine in the art of cancer therapy. For example, Phase I and Phase II clinical trials both focus on determining such parameters, as well as determining the efficacy and toxicity of the administered drug. Thus, the instantly claimed dosing regimens of oral SAHA would have been *prima facie* obvious as they would have been readily determined by the skilled artisan from routine optimization of the methods and dosing schedules disclosed in Richon *et al.*

Claims 1, 7-8, 12-26, 43, 45-49, 119-120, 122, 124, 126, 157 and 169 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Richon *et al.* (US 2003/0235588 A1; Published Dec. 25, 2003) in view of Nilsson *et al.* (Blood, 2000, vol. 95, pages 1420-1426).

The instant claims are drawn to a method of treating chronic lymphocytic leukemia (CLL) comprising oral administration of SAHA.

Richon *et al.* disclose methods of treating thioredoxin (TRX)-mediated diseases by administering to a subject in need of such treatment a therapeutically effective amount of a histone deacetylase (HDAC) inhibitor or a pharmaceutically acceptable salt or hydrate thereof (Abstract). Elevated levels of TRX have been found in cancer. As such, TRX can "stimulate proliferation of a wide variety of cancer cell lines and inhibit apoptosis in cells over-expressing the protein" (page 1, ¶ [0007]). The invention discloses the use of HDAC inhibitors that can alter the expression of a TRX-binding protein (*e.g.* TRX-binding protein-2 or TBP-2), which in turn can lead to altered TRX/TBP-2 cellular binding interaction, resulting in an increase or decrease in the level or activity of cellular TRX (pages 1-2, ¶ [0011]). Thus, the invention relates to the use of HDAC inhibitors in a wide variety of TRX-mediated diseases and conditions, including diseases characterized by cellular hyperproliferation (*id.*).

The inventors discovered that HDAC inhibitors induce expression of a TRX-binding protein, which is associated with a decrease in the level or activity of TRX resulting from interaction of TRX with the TRX-binding protein (page 2, ¶ [0012]). HDAC inhibitors, therefore, can be used to treat diseases characterized by "an increased level or activity of TRX" (page 2, ¶ [0013]). HDAC inhibitors effective at treating TRX-mediated diseases include hydroxamic acid derivatives (page 2, ¶ [0021]), including the instantly claimed SAHA (*id.* at ¶ [0023] and page 3, ¶ [0030]). Pharmaceutically acceptable salts of HDAC inhibitors are recited at page 17, ¶ [0156]. Hydrates of HDAC inhibitors are recited at page 17, ¶ [0157].

HDAC inhibitors of the invention can be administered in oral forms including tablets, capsules, pills, powders, granules, elixers, tinctures, suspensions, syrups, and emulsions (page 18, ¶ [0176]). Oral dosages of the HDAC inhibitors can range between about 2 mg to about 2000 mg per day and specific oral dosages of 2, 20, 200, 400, 800, 1200, 1600, and 2000 mg per day are disclosed (page 19, ¶ [0181]). The reference thus discloses the oral dosages of SAHA instantly claimed. The total daily amount of HDAC inhibitor can be administered in multiple doses, such as twice, three, or four times per day (*id.*). The oral formulations can be in the form of tablets or capsules and combined with pharmaceutically acceptable inert carriers, including microcrystalline cellulose (page 20, ¶ [0191]). In addition, suitable binders, lubricants and disintegrating agents can be included in the formulation (*id.*). Suitable disintegrating agents include the instantly claimed sodium croscarmellose (*id.*). Suitable lubricants include the instantly claimed magnesium stearate (*id.*).

Thus, Richon *et al.* disclose methods of administering the instantly claimed HDAC inhibitor in the doses and formulations instantly claimed. The reference further discloses methods of treating TRX-mediated diseases. The reference does not *explicitly* disclose the treatment of CLL by orally administering SAHA.

However, Nilsson *et al.* provide the nexus between TRX and CLL and further provide the motivation to use the methods disclosed in Richon *et al.* to treat CLL. The reference discloses that TRX prolongs survival of B-type chronic lymphocytic leukemia cells (B-CLL) by increasing the TNF-α, which has been suggested as an autocrine growth factor for CLL cells (Abstract; Figure 5). TRX added to B-CLL cells significantly delayed Bcl-2 (an apoptosis suppressor) down-regulation and diminished the number of apoptotic cells, resulting in prolonged survival

(page 1424, left column, "Discussion"). In contrast to adult T-cell leukemia, which over-expresses TRX, leukemic B-CLL cells do not over-express TRX (*id.*, right column). The authors hypothesize that TRX is supplied by other cells in close contact with the leukemic cells in patients with B-CLL (*id.*).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

In the instant case, the prior art discloses methods of treating TRX-mediated diseases comprising oral administration of HDAC inhibitors in the doses instantly claimed (Richon *et al.*). The prior art also provides the nexus between TRX and CLL (Nilsson *et al.*).

The prior art does not *explicitly* disclose the treatment of CLL comprising the oral administration of SAHA. However, given the scope and contents of the prior art, the instantly claimed methods would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

The level of ordinary skill in the art is that of an M.D., Ph.D. or pharmacist. The skilled artisan would have been aware that B-CLL could be characterized as a TRX-mediated disease given the disclosure of Nilsson *et al.*

It was well known in the art that SAHA is capable of inducing tumor cell growth arrest, differentiation and/or apoptosis (Specification, page 4, lines 29-31). As such, one skilled in the

art would have appreciated that the methods described in Richon *et al.* would be useful in the treatment of cancers wherein TRX is implicated. In fact, Richon *et al.* contemplate such a treatment of diseases characterized by cellular hyperproliferation (*e.g.* cancer).

Given the above analysis, the instantly claimed methods of treating CLL would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Richon *et al.* disclose the instantly claimed HDAC inhibitor as well as oral formulations and doses commensurate in scope with the instant claims. Nilsson *et al.* provide the nexus and motivation to use the methods disclosed in Richon *et al.* to treat B-CLL. As such, the skilled artisan would have had the means and motivation to treat B-CLL with an oral formulation of the HDAC inhibitor, SAHA.

Claims 121, 123, 125 and 164-168 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Richon *et al.* and Nilsson *et al.* as applied to claims 1, 7-8, 12-26, 43, 45-49, 119-120, 122, 124, 126, 157 and 169 above, and further in view of Kelly *et al.* (Proc. American Society of Clinical Oncology, 2001, 20:87a, Abstract No. 344) (cited by applicants in IDS filed 4/6/2004).

This instant claims recite specific administration schedules of oral SAHA.

Richon *et al.* and Nilsson *et al.* disclose as discussed *supra*. The combined references do not disclose the specific administration schedules instantly claimed.

However, Kelly *et al.* is provided as evidence that optimizing administration schedules of SAHA is well within the level of ordinary skill in the art and is therefore routine optimization. The reference discloses the optimization of dosing regimes for intravenous SAHA. SAHA was

administered to patients at varying doses as a 2-hr. IV infusion for three consecutive days every 21 days and for five consecutive days for 1-3 weeks.

The skilled artisan would have been highly motivated to determine the optimal dose and schedule of administration of SAHA for the treatment of CML. It is noted that optimization of drug dosing and scheduling is routine in the art of cancer therapy. For example, Phase I and Phase II clinical trials both focus on determining such parameters, as well as determining the efficacy and toxicity of the administered drug. Thus, the instantly claimed dosing regimes of oral SAHA would have been *prima facie* obvious as they would have been readily determined by the skilled artisan from routine optimization of the methods and dosing schedules disclosed in Richon *et al.*

Duplicate Claims

Applicant is advised that should claims 3-4, 5-6, 8, 9 and 10 be found allowable, claims 27-28, 35-36, 43 and 57 will be objected to under 37 CFR § 1.75 as being a substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

December 20, 2006

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER